POLYMIX

AT THE HEART OF MATERIALS

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POLYMIX

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AMP-POLYMIX Group

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PREVENTING, DIAGNOSING, HEALING

ARE THE KEY OBJECTIVES OF THE HEALTH ACTORS, HOSPITALS AND LABORATORIES

French leader in the distribution of technical polymers,
POLYMIX is more than ever positioned as an innovation finder.
For 40 years, POLYMIX has displayed a know-how
and a multi-skill in the commercialization of thermoplastic materials.

Preventing, diagnosing and healing are the key objectives of health actors, hospitals and laboratories.

POLYMIX supports you in your projects, with a large and diversified range as well as a recognized expertise in medical matters. Our materials meet the requirements of medical and diagnostics devices, pharmaceutical and medical packaging. We support you from the identification of materials to their homologation.

POLYMIX partners are **ISO13485** certified and offer materials in compliance with the pharmacopea regulatories : **ISO10993, USP6, EP3.1, USP661, and FDA Drug Master File.**

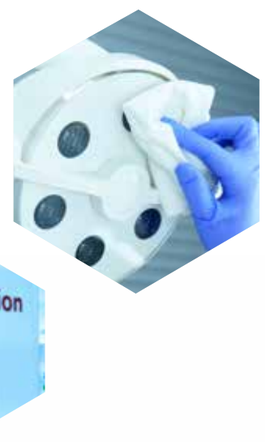
In addition, the inherent properties of thermoplastics offer many solutions for your projects:

- ☑ Transparency or opacity
- ☑ Physical and mechanical properties
- ☑ Hardness and flexibility
- ☑ Modulus
- ☑ Density
- ☑ Thermal properties
- ☑ Tribological properties
- ☑ Improved chemical resistance
- ☑ Lipid resistance
- ☑ Resistance to tearing and percability, breakability of packaging

STERILIZATIONS AND DESINFECTIONS

Concerned about the quality of the medical devices after their sterilization, **POLYMIX** has the expertise and offers tailored solutions according to the different processes intented to **single use and multi-use medical devices**:

- ☑ Ethylene oxide
- ☑ Irradiation : gamma, Xray, E-beam
- ☑ Autoclave
- ☑ Repeated disinfections (solvents)
- ☑ Decontamination : UV-C and antimicrobial solutions



DIAGNOSTIC DEVICES PIPETS, TUBES, CONTAINERS

- ☑ Biocompatibility
- ☑ High transparency

ELECTRONIC AND CONNECTED MEDICAL DEVICES

- ☑ Biocompatibility
- ☑ Improved chemical resistance
- ☑ Aesthetics
- ☑ Halogen free UL94 V0 ignifugation
- ☑ Radio-frequency protection

FLEXIBLE AND RIGID MEDICAL PACKAGING

- ☑ Biocompatibility
- ☑ Transparency
- ☑ Barrier effect
- ☑ Resistance to tearing, piercing and breakability
- ☑ Impact resistance including cold impact

SINGLE-USE MEDICAL DEVICES

- ☑ Biocompatibility
- ☑ Materials for functional components

SURGICAL DEVICES

- ☑ Biocompatibility
- ☑ Metal replacement
- ☑ Aesthetics
- ☑ Increased autoclave capacity (< 2 500 cycles at 134°)

SUSTAINABLE SOLUTIONS

Bio-based and recycled materials
in the respect of the biocompatibility

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			MEDICAL CERTIFICATIONS		STERILIZATION			CHEMICAL RESISTANCE	TRANSPARENT
					GAS	IRRADIATION	AUTOCLAVE		
			ISO10993	USP6	ETO	GAMMA / E-BEAM / X-RAY	134°C		
REPSOL / REPSOL Healthcare	HPP	PP	●	●	●●●	●●○	121°C - 1 cycle	●●●	●
	HPR	PP copo	●	●	●●●	●●○	121°C - 1 cycle	●●●	●
	HPP-RMD / HPR-RMD Improved irradiation	PP / PP copo	●	●	●●●	●●●	121°C - 1 cycle	●●●	●
	HLD	LDPE	●	●	●●●	●●○	○	●●●	●
	HHD	HDPE	●	●	●●●	●●○	121°C - 1 cycle	●●●	●
	HVA	EVA copo	●	●	●●●	●●○	○	●●●	●
Resirene	HH104 MED	PS	○	●	●●●	●●○	○	●○○	●
	6110MED - 6420MED	HIPS	○	●	●●●	●●○	○	●○○	○
	CET®	SMMA	○	●	●●●	●●○	○	●○○	●
INDORAMA VENTURES	RAMAPET® N180 - N1S	PET	●	○	●●●	●●●	○	●●○	●
KPAC Engineering Plastics	KEPITAL™ MX	POM	●	●	●●●	●○○	< 50 cycles	●●●	○
SUSTAINABLE ARKEMA	RILSAN®	PA11	◑	◑	●●●	●●○	< 100 cycles	●●●	○
	RILSAN® CLEAR	PA11 transparent	◑	◑	●●●	●●○	< 100 cycles	●●○	●
	PEBAX®	PEBA	◑	◑	●●●	●●○	< 25 cycles	●●●	◑
SABIC	LEXAN™ HP	PC	●	●	●●●	●●○	< 10 cycles	●○○	●
	LEXAN™ HPS Improved irradiation	PC	●	●	●●●	●●●	< 10 cycles	●○○	●
	CYCOLAC™ HMG	ABS	●	●	●●●	●●○	○	●○○	○
	CYCOLOY™ HC	PC/ABS	●	●	●●●	●●○	○	●○○	○
	XYLEX™ HX	PC/PET	●	●	●●●	●●●	○	●●○	●
	XENOY™ HX	PC/PBT	●	●	●●●	●●●	○	●●○	○
	VALOX™ HX	PBT	●	●	●●●	●●●	○	●●●	○
SUSTAINABLE	LEXAN™ from renewable feedstock Recycled and Bio-based ressources	PC	●	●	●●●	◑	◑	●○○	●

● Yes ○ No ◑ On request ●○○ : limited ●●○ : good ●●● : excellent

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			MEDICAL CERTIFICATIONS		STERILIZATION			CHEMICAL RESISTANCE	TRANSPARENT
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			ISO10993	USP6	ETO	GAMMA / E-BEAM / X-RAY	134°C		
sabic Specialties	LEXAN™ HPX	PC copo	●	●	●●●	●●○	< 100 cycles	●○○	●
	LEXAN™ HPH	PC copo	●	●	●●●	●●○	< 300 cycles	●○○	●
	ELCRES™ CRX	PC copo	○	○	●●●	●●○	< 10 cycles	●●○	●
	ELCRES™ CRX	PC copo/PBT	○	○	●●●	●●●	○	●●●	○
	ELCRES™ CYCOLOY™ CX2244ME	PC copo/ABS	●	●	●●●	●●○	○	●●●	○
	NORYL™ HN	PPO	●	●	●●●	●●●	< 2 500 cycles	●●●	○
	ULTEM® HU	PEI	●	●	●●●	●●●	< 1 000 cycles	●●●	●
优巨新材 YOUJUXINCAI	PARYLS®	PPSU	●	○	●●●	●●○	< 500 cycles	●●●	●
GHARDA PLASTICS	G-PAEK™ 1200G	PEK	●	●	●●●	●●●	< 1500 cycles	●●●	○
GRECO	ISOTHANE® SERIE 3000	TPU ether	●	○	●●●	●○○	○	●●○	●
	ISOTHANE® SERIE 5000	TPU ether	○	●	●●●	●○○	○	●●○	●
PREMIX	PRE-ELEC®	Conductive compounds	◑	◑	●●●	◑	◑	◑	○
AMP CHIMEI	POLYLAC® PA757F	ABS	○	●	●●●	●●○	○	●○○	○
	POLYLAC® 704LRP	ABS	●	○	●●●	●●○	○	●○○	○
	POLYLAC® PA758	MABS	○	●	●●●	●●○	○	●○○	●
	POLYLAC® PA703TRP	MABS	●	○	●●●	●●○	○	●○○	●
	KIBITON® PB-5903	SBC	○	●	●●●	●○○	○	●●○	●

● Yes ○ No ◑ On request ●○○ : limited ●●○ : good ●●● : excellent

ADDITIONAL RANGE

PREXELENT™	**Sustainable Antimicrobial Agent** from pine oil	Purgex Purging Compounds	**Purging compound** for colors and resins change Effectively removes contamination Fast action and non-abrasive Easily removed FDA certified grades

NOTE
ISO 10993 - The ISO 10993, regulated by the International Organization for Standardization (ISO), is a standard series for the biological evaluation of medical devices. The aim of the standard is to evaluate the biological assessment regarding the biocompatibility of the materials with the human body.
Important parts :
· ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
· ISO 10993-11:2006 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
DMF - A Drug Master File (DMF) is a confidential, detailed document about active substances contained in the medical product. It is submitted from manufacturers to the U.S. Food and Drug Administration (FDA). A DMF contains the chemistry, manufacturing and controls of a component of a drug product. There is no legal obligation to create a DMF and to submit it to the authorities.
USP - The United States Pharmacopeia (USP) includes standards to guarantee the quality and purity of medicines and health technologies worldwide. It covers tests relating to the biological reactivity of elastomers, plastics and other polymer materials with direct or indirect customer contact. USP Class VI is the most stringent test and accepted in the sector.

The AMP-POLYMIX Group authorises the use of materials for class I and II medical devices. For class III and/or implantable medical devices (short term, long term and permanent), the use of a material must be subject to a prior negotiated agreement between the different parties.

DISCLAIMER
Any information given on the chemical and physical characteristics of products, including technical advice on applications whether verbally, in writing or by testing the product, is given to the best of our knowledge. It does not exempt the buyer from carrying out his own investigations and tests in order to ascertain the products' specific suitability for the purpose intended. The buyer is solely responsible for the application, utilization and processing of the products and must observe the laws and government regulations and the consequential rights of any third party. At all times our Conditions of Sale apply. Please contact us to inquire availablity per represented countries.

AMP-POLYMIX Group doesn't authorize the use of materials for class III material devices.